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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,093	03/16/2001	Stephanie K. Clendennen	4257-0025.30	8290

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EXAMINER
MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
1638	10

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,093	CLENDENNEN ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2001 and 08 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 7-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 7-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicants' election of the MEL7 promoter, SEQ ID NO: 42, in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, for example at page 20, lines 38 and 39, and page 29, lines 28 and 31. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

3. Claims 13 and 15 are objected to because of the following informalities: the article "a" in the recitation "comprising a melon" in line 1 of claim 13 and line 3 of claim 15 should be --the--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 5, and 7-19 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "characterized by" in line 2 of claim 1 renders the claim and those dependent thereon indefinite. It is not clear exactly what is meant by the recitation. It is suggested that the recitation be replaced with the following: --wherein said promoter has--.

The recitation "MEL7" in claim 1 also renders the claim indefinite. The name "MEL7" is arbitrarily assigned and does not clearly identify the promoter, and there is no claimed description of the promoter that encompasses all of its specific or essential traits that are associated with that denomination. The claim does not set forth the metes and bounds of the invention.

Regarding claims 3 and 18: the recitation "primarily activated" in line 3 of the claims renders them indefinite. It is not clear what is exactly meant by this recitation.

Regarding claim 8: the recitation "operably linked to a heterologous nucleic acid coding sequence" renders the claim indefinite. While a vector can comprise a heterologous nucleic acid coding sequence, it is not clear what is meant by operably linking a vector to a heterologous nucleic acid coding sequence. It is suggested that the recitation --wherein said promoter is-- be inserted before "operably", if it is intended for the promoter to be operably linked to the coding sequence.

Regarding claim 9: the recitation "operably linked to control sequences" renders the claim indefinite. While a vector can comprise any nucleic acid sequence, it is not clear what is meant by operably linking a vector to a control sequence.

Regarding claim 19: the recitation "*sam-k*" renders the claim indefinite. The specification at page 15, in the sentence spanning lines 27-30, indicates that *sam-k* is another name for "SAMase," which is an abbreviation for S-adenosylmethionine hydrolase (page 15, lines 8-11). However, as "*sam-k*" is an arbitrarily assigned abbreviation, it may also be assigned to genes encoding other products. The claim does not make exactly clear that it is referring to the nucleic acid encoding S-adenosylmethionine hydrolase. Further, some of the prior art references cited in the specification, for example Hughes et al. (J. Bacteriol., 1987, Vol. 169, pages 3625-3632; specification, page 15, line 10), refer to the S-adenosylmethionine hydrolase of coliphage T3 as "AdoMetase" or "AdoMet synthetase" (abstract). It is not clear if this coliphage gene is encompassed by the claim. It is suggested that the recitation "is *sam-k*" in line 2 of the claim be amended to --encodes S-adenosylmethionine hydrolase--, if this is Applicants' intent, to clearly and particularly define the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3 and 13-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated nucleic acid sequence comprising any fruit-associated promoter of any MEL7 gene of any melon, wherein the promoter has the ability to promoter fruit-associated expression of a transgene operably linked to it; or wherein the promoter is ethylene regulated; or wherein expression is induced by changes in ethylene concentration in the plant and said promoter is activated or primarily activated during later stages of fruit development and/or early stages of fruit ripening; any plant cell comprising said promoter; any mature plant comprising said plant cell; a method of expressing a heterologous nucleic acid sequence in a plant cell, comprising transforming a plant cell with a nucleic acid construct comprising said promoter operably linked to said heterologous nucleic acid sequence; or wherein growing said transformed plant cells to produce a transgenic fruit-bearing plant.

The specification indicates that the promoter of a gene arbitrarily termed "MEL7" was isolated from cantaloupe fruit, and the nucleotide sequence of the promoter is set forth in SEQ ID NO: 42 (page 23, line 20 to page 25, line 16). RAP screening was used to isolate an abundant transcript, designated "MEL7," from ripe cantaloupe fruit as part of the process to isolate the promoter. The transcript was relatively fruit-specific and ripening-associated (page 11, lines 28-30). The MEL7 promoter of SEQ ID NO: 42 directed expression of GUS in transiently transformed fruit tissue of cantaloupe, apples, pears, and tomato (page 31, line 5 to page 32, Table 4), and directed expression of S-adenosylmethionine hydrolase in fruit of transgenic cantaloupe plants (page 34, line 3 to page 35, line 14). Fruit of transgenic plants showed lower ethylene production versus fruit of non-transgenic control plants (page 35, lines 2-14, Table 9).

However, the specification does not describe any other MEL7 promoters from cantaloupe or other melon plants. The specification does not describe the regions of SEQ ID NO: 42 that

are essential to its fruit-associated promoter activity, and the nucleotide sequence of SEQ ID NO: 42 does not provide any information concerning the structure of other MEL7 fruit-associated promoters of cantaloupe or any other melon plant. Although the specification describes the method used to isolated SEQ ID NO: 42, a method does not describe the structure of any promoter itself. See Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". Given the breadth of the claims encompassing any isolated nucleic acid sequence comprising any fruit-associated promoter of any MEL7 gene of any melon plant, and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of nucleic acids encompassed by the claims.

6. Claims 1-3 and 13-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the MEL7 promoter set forth in SEQ ID NO: 42, and inducing the MEL7 promoter by increasing the concentration of ethylene, does not reasonably provide enablement for any other isolated nucleic acid sequence comprising any other fruit associated promoter of any other MEL7 gene or for inducing the MEL7 promoter by decreasing the concentration of ethylene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any isolated nucleic acid sequence comprising any fruit-associated promoter of any MEL7 gene of any melon, wherein the promoter has the ability to promoter fruit-associated expression of a transgene operably linked to it; or wherein the promoter is ethylene regulated; or wherein expression is induced by changes in ethylene concentration in the plant and said promoter is activated or primarily activated during later stages of fruit development and/or early stages of fruit ripening; any plant cell comprising said promoter; any mature plant comprising said plant cell; a method of expressing a heterologous nucleic acid sequence in a plant cell, comprising transforming a plant cell with a nucleic acid construct comprising said promoter operably linked to said heterologous nucleic acid sequence; or wherein growing said transformed plant cells to produce a transgenic fruit-bearing plant.

As discussed above, the specification teaches the nucleotide sequence of a fruit-associated promoter (SEQ ID NO: 42) of a gene termed "MEL7," isolated from cantaloupe fruit, and the nucleotide sequence of the promoter is set forth in SEQ ID NO: 42 (page 23, line 20 to page 25, line 16). RAP screening was used to isolate an abundant transcript, designated "MEL7," from ripe melon fruit as part of the process to isolate the promoter. The transcript was relatively fruit-specific and ripening-associated (page 11, lines 28—30). The MEL7 promoter of SEQ ID NO: 42 directed expression of an operably linked GUS coding sequence in transiently transformed fruit tissue of melon, apples, pears, and tomato (page 31, line 5 to page 32, Table 4), and directed expression of S-adenosylmethionine hydrolase in fruit of transgenic cantaloupe plants (page 34, line 3 to page 35, line 14). The specification asserts that in ethylene biosynthesis, the immediate precursor of ethylene is produced from S-adenosylmethione by ACC synthase, and that as S-adenosylmethione is depleted, neither ACC nor ethylene is produced.

The specification teaches that a developmental regulation of S-adenosylmethione hydrolase production would allow for an initial climacteric burst of ethylene necessary in fruit, and that a subsequent down regulation of ethylene production would lead to higher quality fruit (page 15, lines 8-42). Fruit of transgenic plants transgenically expressing S-adenosylmethionine hydrolase showed lower ethylene production versus fruit of non-transgenic control plants (page 35, lines 2-14, Table 9).

However, the specification does not teach MEL7 promoters of melon plants other than that set forth in SEQ ID NO: 42. The sequence set forth in SEQ ID NO: 42 does not provide any information regarding the regulatory sequences of all fruit-associated promoters of other MEL7 genes. The specification does not teach MEL7 genes or promoters of melon plants other than cantaloupe. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence). As other MEL7 genes are not taught, their promoters are not taught either. Further, the function of the MEL7 gene from which SEQ ID NO: 42 was derived is unknown (page 24, lines 38-40). In the absence of a function, undue experimentation would be required by one skilled in the art to isolate and identify other genes as "MEL7" from cantaloupe and other melon plants. If a gene cannot be identified as a MEL7 gene, its promoter cannot be identified as a MEL7 promoter either. Furthermore, there is no teaching in the specification that the MEL7 promoter is negatively regulated by ethylene. The claims, however, encompass regulating the MEL7 promoter in any manner or inducing the MEL7 promoter by changing the concentration of ethylene in any manner. Aggelis et al. (Plant Mol. Biol, 1997, Vol. 33, pages 313-322) teach that

MEL7 RNA was induced when unripe fruits were placed in a high ethylene atmosphere (page 317, second column, and page 318, second column). As MEL7 is induced by ethylene, undue experimentation would be required by one skilled in the art to negatively regulate the MEL7 promoter with increasing concentrations of ethylene, or to induce it by decreasing the concentration of ethylene. It is suggested that claims 2, 3, and 18 be amended to indicate that expression by the MEL7 promoter is induced by increasing the concentration of ethylene. Given the breadth of the claims encompassing any isolated nucleic acid sequence comprising any fruit-associated promoter of any MEL7 gene from any melon plant, and regulating the MEL7 promoter by changing the concentration of ethylene in any manner, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

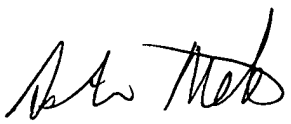
Summary

7. Claims 1-3, 5, and 7-19 are deemed free of the prior art, given the failure of the prior art to teach or fairly suggest isolated nucleic acid sequences comprising a melon fruit-associated MEL7 promoter. Aggelis et al. (Plant Molecular Biology, 1997, Vol. 33, pages 313-322) teach the cantaloupe MEL7 cDNA clone, and that a Southern analysis of cantaloupe genomic DNA was conducted using a MEL7 radiolabelled probe. However, neither the corresponding genomic clone nor the MEL7 promoter was taught.

8. No claim is allowed.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

May 6, 2002